REMARKS

Claims 1, 4, 6-7, 10-11, 14-15, 17-26 and 28-30 are pending in the present application. Applicant notes with appreciation the indication that claims 18-19 and 29 are allowable.

In the outstanding Official Action, claims 1, 4, 6-7, 10-11, 14-15, 17 and 22-26 were rejected under 35 USC §112, first paragraph, for allegedly not satisfying the written description requirement. This rejection is respectfully traversed.

In imposing the rejection, the Official Action alleges that the present specification only discloses a fragment of a full length protein. The Official Action further contends that without the disclosure of the full length protein, applicant's written description is only adequately described for the identified fragment.

However, the Examiner's attention is respectfully directed to page 10, lines 5-28, wherein it is noted that the present invention is directed to an isolated mite-derived protein, which is an antigen derived from the mite *Sarcoptes scabiei*. More specifically, the present disclosure teaches that the proteins comprise amino acids from a protein that has been denoted Major Sarcoptes Antigen 1 (MSA1). The present disclosure further teaches that MSA1 corresponds to a native 164 kDa protein, which provides a rapid immunogenic response in dogs.

Thus, the present disclosure plainly teaches that the present invention is related to more than just a single fragment.

At this time, the Examiner is respectfully reminded that the determination of what is needed to support claims to biological subject matter depends on numerous factors, such as the existing knowledge in the particular field, the extend of the prior art, the extent of the science or technology, the predictability of the matter at issue, and other considerations appropriate to the subject matter. See, e.g., *In re Wallach*, 378 F.3d 1330, 1333-34 (Fed. Cir. 2004) (an amino acid sequence supports "the entire genus of DNA sequences" that can encode the amino acid sequence because "the state of the art has developed" such that it is a routine matter to convert one to the other); *University of Rochester*, 358 F.3d at 925, *Singh v. Brake*, 317 F.3d 1334, 1343 (Fed. Cir. 2003).

It is not necessary that every permutation within a generally operable invention be effective in order for an inventor to obtain a generic claim, provided that the effect is sufficiently characterized to form a generic invention. See *In re Angstadt*, 537 F.2d 498, 504 (CCPA 1976). While the Patent Office is correct that a generic invention requires adequate support, the sufficiency of the support must be determined on a case by case basis. As acknowledged by the Official Action, the present disclosure explicitly teaches the claimed sequence. In view of the expressly explicitly recited sequence and the

knowledge that it relates to mite-derived proteins, applicant believes that the present disclosure satisfies the written description requirement.

As a result, applicant respectfully requests that the written description rejection be withdrawn.

Claims 20-21 were rejected under 35 USC §112, first paragraph, for allegedly not satisfying the enablement requirement. This rejection is respectfully traversed.

In imposing the rejection, the Official Action states that while the specification is enabling for an immunogenic composition consisting of SEQ ID NO: 2, the present disclosure does not reasonably provide enablement for methods of treatment comprising administering compositions consisting of SEQ ID NO: 2. In further support of its position, the Patent Office cites to PLOTKIN et al. for the proposition that those skilled in the art would recognize that it is unpredictable whether a single protein derived from a pathogen will elicit protective immunity.

However, as noted above, the present disclosure teaches that the present invention relates to isolated mite-derived proteins, which are antigens derived from the mite *Sarcoptes scabiei*. Furthermore, the specification teaches that the proteins of the present invention comprise amino acids from the MSA1, which corresponds to a native protein, which provides a rapid immunogenic response in animals. Thus, applicant believes that the present disclosure provides the proper guidance to

utilize the claimed compositions for the treatment of a disease associated with mites.

Indeed, applicant respectfully submits that the Patent Office does not provide any evidence to the contrary.

It is a well founded principle that any assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubt so expressed.

As a matter of law, the expressed teaching of the patent specification cannot be controverted by mere speculation and unsupported assertions on the part of the Patent Office. As stated by the Court of Customs and Patent Appeals in the case of *In re Dinh-Nguyen and Stanhagen,* 181 USPQ 46 (CCPA 1974):

> Any assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubt so expressed. 181 USPQ at 47.

Such a standard must be applied with great care when the Examiner's conjecture is contrary to the teachings of the specification.

While the Official Action cites to the excerpt from the textbook "VACCINES" by PLOTKIN et al. as supporting the rejection, the excerpt relates to the use of recombinant DNA technology in the development of vaccines. The excerpt does not relate to isolated mite-derived proteins or cast any doubt as to

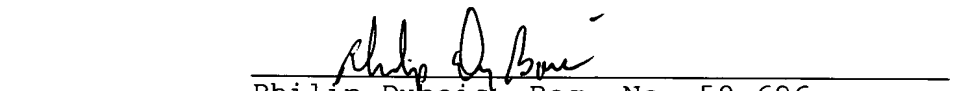
the teachings of the present specification at page 9, line 29 to page 10, line 28 or page 21, lines 9-27. Thus, in view of the above, applicant believes that the Patent Office fails to satisfy its burden in showing that the present disclosure is not enabling for claims 20 and 21.

In view of the present amendment and the foregoing remarks, therefore, applicant believes that the present application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



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